In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 14-626V

(not to be published)

JESSICA PLOUGHE, *natural mother and guardian of S.P., a minor*, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES Respondent.	Chief Special Master Corcoran Filed: February 18, 2020 Rash; Onset; Developmental delay and autism injuries

Jessica Ploughe, Ridgeville, SC, *pro se* Petitioner.

Christine Becer, U.S. Dep't of Justice, Washington, DC, for Respondent.

DECISION[1]

On July 18, 2014, Jessica Ploughe filed a petition seeking compensation under the National Vaccine Injury Compensation Program ("Vaccine Program")[2] alleging that her daughter, S.P., experienced an allergy, chronic/recurrent rash, and associated gastrointestinal problems attributable to several vaccines she received on July 22, 2011. Petition ("Pet.") (ECF No. 1) at 1. The parties acceded to my determination that the matter could appropriately be resolved by a ruling

[1] Although I have not formally designated this Decision for publication, it will nevertheless be posted on the Court of Federal Claims' website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012)). **This means that the Decision will be available to anyone with access to the internet.** As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter "Vaccine Act" or "the Act"]. Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

on the record. Now, after review of all submissions in the case, I deny an entitlement award. As discussed in greater detail below, Petitioner has not successfully established that the various symptoms she alleges S.P. experienced were the product of a vaccine-initiated injury.

I. Factual Background

Pre-Vaccination History

S.P. was born on February 18, 2010, with no complications or noted risks. Ex. 6 at 130–39. Her first year of life was characterized by few medical concerns. Ex. 4 at 15–16; Ex. 2 at 5–8. At most, she was observed to have erythema[3] at her March 2010 well-child visit (Ex. 4 at 14), and (because her mother was a smoker) was throughout this time regularly exposed to secondhand smoke in her home. Ex. 6 at 49. S.P. received some vaccinations in this initial period of life as well, with no reported reaction or complications. Ex. 2 at 8.

In the spring of 2011, S.P. (now over twelve months old) was taken by Petitioner to a hospital emergency room due to a high fever and cough, and was subsequently diagnosed with pneumonia. Ex. 6 at 73–74. At an April 2011 follow-up with her pediatrician, she was reported to have again recently experienced a high fever, and was prescribed antibiotics in response. Ex. 2 at 10. Then, at a subsequent pediatric visit the following month, S.P. displayed symptoms of coughing and nasal discharge but no high fever and no other associated symptoms. Ex. 2 at 26–28. This lead her treater to assess her with streptococcal pharyngitis and an acute upper respiratory infection, and to prescribe additional antibiotics. *Id.* She experienced additional similar respiratory symptoms toward the end of May 2011, with a comparable differential diagnosis. *Id.* at 29, 31; *see also* Ex. 6 at 47, 49, 71 (records from May 25, 2011 ER visit, prompted by breathing concerns).

In the following first two months of summer (right before receiving the vaccines in question), S.P. had several additional medical encounters. Some reflect reasonable parental concerns about infant health that were not corroborated by positive diagnoses of illness, or reflected merely another URI. *See, e.g.*, Ex. 2 at 32 (May 26, 2011 call to pediatrician), 33 (May 27, 2011 visit), 36 (June 3, 2011 visit), 44–46 (July 11, 2011 visit, prompted by S.P. pulling on her ears). S.P. also had another ER visit prompted by a physical accident at home. Ex. 3 at 13–14. In mid-July, 2011, however, S.P. was again brought to her pediatrician in part due to a rash (evidenced by "erythematous papules," or red bumps, or her back and legs) that had manifested a week before. *Id.* at 47. S.P. had no other concerning symptoms (beyond the consistent respiratory issues previously reported), so the treating pediatrician diagnosed her with viral exanthem and an upper respiratory infection, and prescribed a topical cream for the rash. *Id.* at 49.

[3] Erythema is "redness of the skin produced by congestion of the capillaries." *Dorland's Illustrated Medical Dictionary* 636 (33d ed. 2020) (Dorland's).

Vaccination Visit and Immediate Subsequent History

On July 22, 2011, S.P. was taken back to the pediatrician for her 18-month well child visit. Ex. 2 at 50. No medical or developmental concerns were reported, although she still had a rash on her back, similar to what she had displayed the week prior. *Id.* She received the hepatitis B; measles, mumps, and rubella virus; Pentacel (containing diphtheria and tetanus toxoids and acellular pertussis adsorbed, inactivated poliovirus and haemophilus b conjugate (tetanus toxoid conjugate)); pneumococcal; and Varicella vaccines. *Id.* at 52. A specialized test was also ordered to assess any developmental delay or concerns. *Id.* at 52, 55. S.P. was prescribed a different topical ointment for her rash. *Id.* at 52. The records do not detail any immediate reaction to these vaccinations. Her parents did place a call to the pediatrician two days later, when S.P. had been vomiting, but it does not appear that a follow-up visit was required. *Id.* at 54.

On August 1, 2011, S.P. again saw her pediatrician after experiencing a fairly high fever (between 101 and 103 degrees) plus poor appetite, suggesting to Mrs. Ploughe that S.P. might again have strep throat. Ex. 2 at 56. However, a rapid strep test came back negative. *Id.* at 58. In addition, the notes from this visit do not record the presence of a rash at this time, and also confirm that S.P. had not experienced any noticeable reaction to the July 22nd vaccines she had received ten days prior. *Id.* at 56, 58. But the rash was present again at yet another pediatric visit on August 9, 2011—with treaters now being informed (contrary to the August 1st records) that it had developed over the prior two weeks. *Id.* at 64. S.P. was again assessed with viral exanthem, and told to continue with previously-prescribed topical medications, plus Benadryl for itchiness. *Id.* at 66. S.P. had an additional hospital visit two days later, motivated by the rash plus some respiratory issues, and then another pediatric visit on August 15th—none of which resulted in any diagnoses that suggested treaters were sufficiently concerned about S.P.'s health to warrant greater intervention efforts. Ex. 3 at 4, 6 (August 10, 2011 hospital visit); Ex. 2 at 60, 62–63 (August 15, 2011 pediatric visit).

There is subsequently a more than three-month gap in the medical record, with no additional contact with S.P.s' treaters until December 1, 2011, when Mrs. Ploughe called the pediatrician to report S.P. was vomiting and again running a fever. Ex. 2 at 67. This did not prompt any immediate follow-up visit, but S.P. did see her pediatrician on December 5, 2011, at which time loose stools, a fever, and ear pulling were reported. Ex. 2 at 68. The treating physician assessed S.P. with a likely viral syndrome and instructed Petitioner to return if symptoms worsened. *Id.* at 70.

Treatment in 2013

The first medical record from 2013 relevant to the claim is from May 9, 2013, when S.P. (now over three years old) had a physical examination. Ex. 4 at 7. Current concerns expressed related to speech, gastrointestinal issues (alternating between diarrhea and constipation), and temperament problems, along with a reported food intolerance. *Id.* Testing was negative for celiac

disease and other disorders, however. *Id.* at 12. The medical history then jumps forward four months, to October 15, 2013, when S.P. appeared to be suffering from an ear infection. Ex. 4 at 2. On physical exam, the treating physician noted that S.P. seemed withdrawn and did not allow the examiner to examine her, in addition to appearing overweight. *Id.* The doctor diagnosed S.P. with irritable bowel syndrome variant of childhood with constipation. *Id.*

In the second half of October 2013, S.P. was seen by Jeffery J. Kline, M.D., to evaluate her reported abdominal pain, occasional constipation, acid reflux, diarrhea, and a possible milk allergy. Ex. 5 at 5. A general examination, however, produced normal results, and she was primarily assessed with reflux. *Id.* at 6. The following month, on November 22, 2013, S.P. was treated for second-degree burns on her back/buttocks caused by an accidental fall into a hot fireplace glass door. Ex. 6 at 18. Her health history now noted (for the first time) that S.P. had previously experienced immunization reactions. *Id.* at 21. Healthcare professionals discussed the risks and benefits of S.P. having the tetanus shot after a burn, but Mrs. Ploughe declined to do so. *Id.* at 20.

Subsequent Treatment and Developmental Concerns

The records filed in this case from 2014 onward (and hence after this case's initiation) address additional care S.P. received, as well as testing performed to evaluate possible causes of her condition. Many of these records reveal the primary concerns at this time were not a rash or other purported vaccine reaction beginning in 2011, but rather developmental delay that Mrs. Ploughe seems to have attributed in some part to vaccines.

Thus, on August 18, 2014, S.P. (who was now over four years old) had an annual checkup. Ex. 8 at 7–8. The main concern expressed by Petitioner was "regression"—S.P. was still in diapers, not potty trained (and thus not in school), would bang her head, exhibited severe behavior issues, and was developmentally delayed. *Id.* at 7. Mrs. Ploughe stated at this time that that she suspected S.P. got the entire family sick because S.P. had been exposed to vaccines, and that she did not "want [S.P.] tested for autism [because] she is [in] vaccine court." *Id.* at 7. S.P. was also seen that fall for continued concerns about purported food allergies that might explain her persistent rashes. Ex. 7 at 18. Petitioner again stated that "none of this happened until" S.P.'s July 2011 immunizations, which she maintained had caused her to develop a full-body rash. *Id.*

In early November 2014, Mrs. Ploughe took S.P. to Allan D. Liberman, M.D., and William J. Weirs, M.D., at the Center for Occupational & Environmental Medicine, P.A. Ex. 11 at 9. Petitioner indicated a variety of health concerns as the reason for the visit—vaccine reaction and side effects, metals, diet intake, hair loss, gastrointestinal issues, the inability to potty train, behavior issues, lack of social skill, constant crying, tongue movements, and screaming fits. *Id.* at 9. Petitioner was instructed that S.P. needed to "reduce her total allergic load," and that "[t]his is a perfect example of the spreading phenomenon." *Id.* at 12. The doctors recommended that S.P. receive more laboratory tests, nutritional supplements, and other therapies. *Id.*

Since then, Petitioner has continued to seek treatment for S.P.'s various symptoms, including her developmental delay. *See, e.g.*, Ex. 14 at 4. She has informed treaters that S.P. had an adverse reaction to vaccines at seventeen months old "including vomiting, a pox like rash and then did not tolerate milk when she previously had." *Id.* Testing performed on S.P. to evaluate possible explanations for her non-developmental symptoms has, however, been inconclusive.[4]

II. Expert Reports

Several experts have weighed in on this case: three for Petitioner (John J. Santoro, D.O., Tetyana Obukhanych, Ph.D., and Allan D. Lieberman, M.D.), and one for Respondent (Chris A. Liacouras, M.D.).

A. *Petitioner's Experts*

1. Dr. Santoro

John J. Santoro, D.O., submitted two expert reports on behalf of Petitioner. Report, dated December 3, 2015, filed as Ex. 17 (ECF No. 46-1) ('Santoro Rep."); Report, dated May 15, 2016, filed as Ex. 26 (ECF No. 56-1) ("Santoro Supp. Rep."). His primary area of expertise is Gastroenterology.

Dr. Santoro received his undergraduate degree in Biology at LaSalle College in 1973. Santoro CV, filed on December 4, 2015, as Ex. 22 (ECF No. 47-1). He graduated from Philadelphia College of Osteopathic Medicine in 1978, and completed a rotating internship at John F. Kennedy Memorial Hospital in Stanford New Jersey in 1979. *Id.* at 1 He finished his residency in internal medicine at University of Medicine & Dentistry, NJ School of Osteopathic Medicine, and John F. Kennedy Memorial Hospital in 1981. *Id.* He completed a fellowship in Gastroenterology at University of Medicine & Dentistry, NJ School of Osteopathic Medicine in 1983. *Id.* at 2.

Dr. Santoro is board certified by the American Osteopathic Board of Internal Medicine in internal medicine and gastroenterology. Santoro CV at 2. He is a fellow of the American college of Gastroenterology, the American College of Osteopathic Internists, and the American Gastroenterology Association. *Id.* Dr. Santoro holds numerous awards and positions

[4] In 2015, labs were ordered to rule out celiac, thyroid disorder, and electrolyte imbalance. Ex. 14 at 6. The treating professional opined that if the testing was negative then the most likely cause of constipation was diet related. *Id.* The same professional also opined that throat pain was possible reflux related and EoE, H. pylori could be causing the reflux. *Id.* But S.P. did not test positive for thyroid disorder, celiac, or H. plyori. *Id.* at 8–11. In addition, on July 27, 2016, S.P. returned to Dr. Liberman. Ex. 30. She was diagnosed with Pyroluria, which was confirmed by lab tests. *Id.* at 1, 5. There seems to be some controversy as to what Pyroluria is—or if it is a legitimate diagnosis. However, it is believed to be caused by high hydroxyhermopyrrolin-2-one, and can cause various neurobehavioral issues. *See* Pyrrole Disorder – an Overview, https://mindd.org/pyrrole-article/# (last visited Feb. 13, 2020). S.P. still suffered from stomach pain and constipation. Lab results show very high pyrroles in S.P.'s urine, but were negative in other respects. *Id.* at 5-6.

(administrative and teaching) related to gastroenterology. *Id.* He currently serves as a clinical associate professor of medicine at Rowan University School of Osteopathic Medicine. *Id.* at 3.

In his first report, Dr. Santoro considered whether the constellation of S.P.'s symptoms could be attributed to the vaccines she received in July 2011. *See generally* Santoro Rep. His analysis focused on three categories: (1) S.P.'s acute and chronic gastrointestinal illnesses after vaccination; (2) S.P.'s food allergies; and (3) S.P.'s rash. *Id.* at 3–4. Dr. Santoro opined that vaccines were causative of all three. *Id.* at 5.

First, Dr. Santoro opined that S.P.'s acute and chronic gastrointestinal illnesses were likely caused by the vaccines she received. Santoro Rep. at 3. He notes that nausea, vomiting, abdominal pain. and diarrhea are potential side effects of vaccines. *Id.* Such side effects occur in about one-in-four patients, can be associated with joint and muscle pain, generally occur one to three days after vaccination, and tend to be temporary or short lived. *Id.* Also, although chronic gastrointestinal symptomatology is rare, it is documented. *Id.* (citing N. Thompson et al., *Is Measles Vaccination a Risk Factor for Inflammatory Bowel Disease?* 29 Lancet 345 (1995), filed on Dec. 8, 2015, as Ex. 23 (ECF No. 48-1). That kind of symptom could therefore linger beyond the date of vaccination.

Second, Dr. Santoro opined that S.P.'s food allergies were caused by the vaccine she received. Santoro Rep. at 3. In support, Dr. Santoro cited two articles. The first reviewed twenty-six children who had systemic immediate-type reactions to vaccines. Santoro Rep. at 3 (citing M. Sakaguchi et al., *Food Allergy to Gelatin in Children with Systemic Immediate-type Reactions, Including Anaphylaxis, to Vaccines* 89 J. of Allergy & Clinical Immunology 1058 (1996), filed on Mar. 18, 2016, as Ex. 19 (ECF No. 54-2) ("Sakaguchi"). That study found that twenty-four of twenty-six children who had who had received the measles, mumps, or rubella vaccine and experienced severe reactions to the vaccines also tested positive for a particular antibody, IgE to gelatin. Sakaguchi at 1060 (finding 1.2 to 250 Ua/Ml of anti-gelatin IgE in twenty-four of twenty-six children). The control group—children who had no allergic reaction to vaccine—had no anti-gelatin IgE antibodies. *Id.* Its authors speculated that "[w]e think that the children with allergic reactions to vaccine had been immunized by the gelatin both in the vaccines and foods, and a sensitivity to gelatin developed," but concluded that more investigation was required. *Id.* at 1061.

The other article addresses post-vaccination "ASIA" (autoimmune/inflammatory syndrome induced by adjuvants).[5] Santoro Rep. at 3 (citing A. Soriano et al., *Predicting Post-vaccination Autoimmunity: Who Might be at Risk?* 92 Pharmacological Research 18 (2015) ("Soriano") (not filed by Petitioner). Soriano proposed that a serious allergic reaction is probable

[5] In other cases, I have found that ASIA is not a well-founded medical theory. *See, e.g., Pearson v. Sec'y of Health & Human Servs.*, No. 14-489V, 2019 WL 1150044 at *11 (Fed. Cl. Spec. Mstr. Feb. 7, 2019) (citing *Morris v. Sec'y of Health & Human Servs.*, No. 12-415V, 2016 WL 3022141, at *12 (Fed. Cl. Spec. Mstr. Apr. 1, 2016) (discussing lack of reliability of ASIA theory)); *Johnson v. Sec'y of Health & Human Servs.*, No. 14-254, 2018 WL 2051760, at *7 n.11 (Fed. Cl. Spec. Mstr. Mar. 23, 2018).

if gelatin or egg proteins are used in vaccine formulation, and this risk is allegedly increased by vaccine immunogen contents including adjuvants. *Id.* (citing Soriano). Dr. Santoro's conclusion implies that the two cited articles support the proposition that S.P.'s egg, wheat, and yeast allergies are directly attributable to the vaccines she received in July 2011. *Id.* at 5. But he does not explain how the articles relate to S.P., does not relate autoimmunity to S.P.'s purported allergies, and does not opine that S.P.'s alleged milk allergy was also caused by vaccination. *Id.*

Third, Dr. Santoro opined that S.P.'s rash was also caused by the vaccines she received. Santoro Rep. at 4. He deemed such a reaction common, but also proposed that S.P.'s rash was consistent with Gianotto-Crosti syndrome ("GCS")[6], which has specifically been reported post-vaccination. *Id.* (citing M. Retrouvey, *Gianotto-Crosti Syndrome Following Childhood Vaccinations,* 30 Pediatric Dermatology 137 (2013), filed on Mar. 18, 2016, as Ex. 21 (ECF No. 54-4) ("Retrouvey")). Retrouvey is a case report of a 19-month old infant diagnosed with GCS on his left thigh following administration of the measles, mumps, rubella, DTaP, and Varivax vaccines. Retrouvey at 137. DTaP and Varivax were administered to the child's left thigh and the other vaccines were administered on the right thigh, causing Retrouvey to speculate that DTaP and Varivax were associated with the GCS. *Id.* Retrouvey also listed 12 other case reports associating GCS with vaccination. *Id.* The article concludes that "[a]s the number of childhood symptoms increases and more combination vaccines are available, perhaps we will see further reports of this postimmunization phenomenon." *Id.* at 138.

Finally, Dr. Santoro opined that the timing of S.P's reaction and (purportedly) post-vaccination rash was medically acceptable, attributing her experience to "the high vaccine load." Santoro Rep. at 5. This was especially so "in light of the recent research linking autoimmune and inflammatory syndrome induced by adjuvant vaccines." *Id.* However, when discussing S.P.'s injuries, Dr. Santoro does not explain how the cited materials apply to S.P. *See id.* at 4–6. Rather, he implies that evidence of the reaction and rash alone are sufficient proof of vaccine causality. *See id.*

Dr. Santoro's supplemental report is mostly a response to criticism from Respondent's expert, Dr. Liacouras, of his initial report. Dr. Santoro clarifies his view that S.P. "probably suffers from chronic GERD." Santoro Supp. Rep. at 1. He explained that S.P.'s chronic GERD could be caused by a weakened esophageal sphincter muscle and S.P.'s weakened esophageal sphincter muscle was caused by recurrent episodes of vomiting. *Id.* Dr. Santoro also opined that S.P. most

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[6] GCS is defined as:

> [A] viral disease of young children, generally benign and self-limited, characterized by skin-colored or reddish flat-topped, firm papules forming a symmetrical distribution in an acral distribution, usually on the face, buttocks, or limbs, including the palms and soles. Symptoms are mild; the child may have malaise and a low-grade fever. Several different viruses may cause it, but most commonly the hepatitis B virus.

Dorland's, at 1801.

likely had chronic irritable bowel syndrome. *Id.* at 2. Dr. Santoro concedes that a definite link between vaccination and irritable bowel syndrome has not been reported, but maintained that "a well-documented GI entity of post infectious irritable bowel syndrome supports this possibility." *Id.* (citing C. Errickson et al., *Post Infectious Irritable Bowel Syndrome*, 46 Clinical Infectious Disease 594 (2008) (not filed by Petitioner)). He further speculates that the vaccines S.P. received could trigger an immunologic response in her intestinal tract resulting in longstanding chronic GI infections similar to that of post infectious irritable bowel syndrome, although his analysis does not explain how this would occur. *Id.*

Dr. Santoro next defends his opinion that S.P.'s food allergies were vaccine-caused. Santoro Supp. Rep. at 2. He argues that it is well established that vaccines containing animal proteins can provoke allergy to those same proteins. *Id.* In support, he references the work of Charles Richet, and a 2011 report from the Institute of Medicine. *Id.* (citations omitted). He goes on to argue—as he did in his initial report—that the presence of adjuvants in vaccines increases the immunogenicity of food proteins present in vaccines, and therefore increases the risk of an allergic reaction to those proteins. *Id.* at 2–3 (citing V. Arumugham, *Evidence that Food Proteins in Vaccines Cause the Development of Food Allergies and Its Implications for Vaccine Policy* 4 J. of Developing Drugs 137 (2015); Institute of Medicine Childhood Immunization Schedule and Safety: Stakeholder Concern, Scientific Evidence and Future Studies (Jan. 16, 2013) filed on Jan. 17, 2017, as Ex. 27 (ECF No. 62-1)).

Finally, Dr. Santoro defends his opinion that S.P.'s rash was GCS. Santoro Supp. Rep. at 3. His defense is based on twenty-two pictures of S.P.'s rash that he had seen—but claimed Dr. Liacouras had not seen. *Id.* His proposed diagnosis also arises from the assertions of Petitioner, whom he deemed truthful and factual when describing S.P.'s condition and symptoms. *Id.*

2. Dr. Obukhanych

Tetyana Obukhanych, Ph.D., submitted one expert report on behalf of Petitioner. Report, dated July 3, 2017, filed as Ex. 32 (ECF No. 70-2) ("Obukahanych Rep."). She received her B.A. in biochemistry from Mount Holyoke College in 1999. Obukhanych CV at 1. In 2006 she earned her Ph.D. from The Rockefeller University, Laboratory of Molecular Immunology, with a thesis on "Immunologic Memory to Polysaccharide Antigens." *Id.* She was a postdoctoral research fellow at the Immune Disease Institute from 2006 to 2007 and a postdoctoral research fellow at Stanford University School of Medicine from 2009 to 2012. *Id.* She has co-authored a handful of publications in peer reviewed journals between 2002 and 2012, on developmental biology, immunology, and autism. *Id.* at 1–2.

Dr. Obukhanych opined that S.P. had been "'immunized' against casein by receiving the primary series of casein-contaminated Pentacel." Obukhanych Rep. at 2. This caused S.P. to "develop non-IgE-[mediated GI food allergy ("non-IgE-GIFA")] to dietary casein, which further led to her acute and chronic GI symptoms." *Id.* She mentioned three non-IgE-GIFA processes that

could cause this: (1) food protein-induced enterocolitis syndrome ("FPIES"); (2) food-protein-induced allergic proctocolitis ("FPIAP"); and (3) food protein-induced enteropathy ("FPE"). *Id.* at 5. Dr. Obukhanych focused the most on FPIES. *Id.*

Dr. Obukhanych further proposed that vaccines (particularly those containing adjuvants) contaminated with proteins like casein could inadvertently "immunize" recipients to the contaminant. Obukhanych Rep. at 7–8. S.P. received Pentacel, which has been shown to be contaminated with casein. *Id.* at 6–7. S.P. developed symptoms similar to a stomach bug, which are the hallmark of a non-IgE-mediated gastrointestinal allergy to food proteins. In addition, she proposed that S.P. reacted to the vaccines in a medically-acceptable timeframe consistent with a non-IgE-GIFA response. *Id.* at 1–2.

3. Dr. Lieberman

Petitioner filed Dr. Lieberman's Report on February 1, 2019. (ECF No. 102) ("Lieberman Rep."). A CV for Dr. Lieberman was not submitted, but a summary of his background is available online. *See* https://coem.com/staff/dr-allan-lieberman/ (last visited Feb. 10, 2020). According to his online biography, Dr. Lieberman earned his Doctor of Medicine at Chicago Medical School in 1960. *Id.* Thereafter he "continued training at Mount Saini Hospital in Chicago, Il[linois]" as an intern, resident, and fellow. *Id.* His residencies were in pediatrics and pathology. *Id.* His fellowship was in pathology. *Id.* For the past thirty-six years he has specialized in "Environmental Medicine and Toxicology" and had been in private practice at his "Center for Occupational and Environmental Medicine (which he co-founded). *Id.*

Dr. Lieberman opines that S.P.'s purported food allergies were caused by the vaccines she received. Lieberman Rep. at 4–5.[7] He observes that she had no food sensitivity before vaccination, but manifested problems not long after receipt of the vaccines at issue in July 2011. *Id.* However, for causation Dr. Lieberman relies heavily on the opinion of Dr. Obukhanych. *Id.* at 4. With respect to S.P.'s rash, Dr. Lieberman opines that S.P. experienced a varicella infection directly attributable to the same vaccine. *Id.* at 5. But he does not explain how he reached this conclusion—only that he did so after "careful review." *Id.*

B. *Respondent's Expert - Dr. Liacouras*

Dr. Liacouras submitted two expert reports on behalf of Respondent. Report, dated Feb. 3, 2016, filed as Ex. A (ECF No. 50-1) ("Liacouras Rep."); Report, dated Oct. 25, 2017, filed as Ex. M (ECF No. 77-1) ("Liacouras Supp. Rep."). Dr. Liacouras disputes the conclusion that S.P.'s

[7] Dr. Lieberman also asserted that S.P. has autism caused by her vaccinations. Lieberman Rep.at 1–3. Dr. Liberman states that vaccines can "contribute to microglial activation and neuroinflammation in the brain of patients with autism." *Id.* at 3. But because Petitioner no longer (openly) asserts autism as an injury in this case, I do not address this aspect of his opinion.

rash or purported food allergies have any connection with her July 2011 vaccinations. Liacouras Rep. at 3, 6.

Dr. Liacouras earned his B.A. from Johns Hopkins University in 1981 and his M.D. from Harvard University in 1985. Liacouras CV, filed on February 8, 2016, filed as Ex. B (ECF No. 50-2). Dr. Liacouras did all his postgraduate training and fellowship appointments at the Children's Hospital of Philadelphia. *Id.* at 1. First, he served as an intern from 1985 to 1986, then as a junior and senior resident from 1986 to 1987. *Id.* Finally, he served as a postdoctoral fellow in pediatric gastroenterology and nutrition from 1988 to 1991. *Id.* Dr. Liacouras has held various faculty and hospital appointments over the course of his career. *Id.* at 1–2. Currently, and most relevantly, he serves as professor of pediatrics at Children's Hospital of Philadelphia and as co-director at the Center for Pediatric Eosinophilic Disorders. *Id.* at 2. He has previously held multiple teaching positions and appointments related to pediatrics and gastroenterology. *Id.* Dr. Liacouras is licensed to practice medicine in Pennsylvania and is board certified in pediatrics and gastroenterology. *Id.* Dr. Liacouras has also held editorial positions, co-authored peer reviewed articles, and lectured on subjects related to pediatrics, gastroenterology, and other medical subjects. *See generally id.*

In opining that the vaccines at issue were not causal of injury, Dr. Liacouras deemed significant the fact that S.P. "had no significant, acute symptoms after her first vaccine administration on October 20, 2010." Liacouras Rep. at 3. He also emphasized S.P.'s history of "frequent, intermittent infections" between her first vaccine administrations in October 2010 and her second round on July 22, 2011. *Id.* And he pointed out that S.P. displayed an erythematous popular rash on July 15, 2011—a *week before* S.P.'s July 2011 vaccinations. *Id.* She thereafter experienced no medical complaints that could be attributable to vaccines, beyond an immediate instance of vomiting, which resolved with no other subsequent reported symptoms. *Id.* And the conditions S.P. purportedly has experienced (rash, food allergy, and behavioral/developmental issues) either existed prior to vaccination or arose more than a year after.

Dr. Liacouras also sought to clarify S.P.'s proper diagnoses (and in so doing disputed Dr. Santoro's proposals). First, he opined that S.P. had GERD, and not an inflammatory bowel disease. Liacouras Rep. at 3–4. Second, he noted that S.P. had no history of anaphylactic reaction to foods or a histologic gastrointestinal eosinophilia, thus undercutting the assertion that S.P. suffered from food sensitivities. *Id.* at 4. Third, S.P.'s rash was in his reading of the record related to viral exanthems rather than reflective of GCS. *Id.* at 5. Dr. Liacouras reasoned that S.P.'s rash was better explained by viral exanthems, since the record establishes the rash predated vaccination. *Id.* at 5. Dr. Liacouras also responded to many of the bases for assertions in Dr. Santoro's expert report, critiquing its sources and inferences. Liacouras Rep. at 5–6.

Dr. Liacouras's supplemental report responded to Dr. Obukhanych's report. In it, he explained that FPIES cannot explain S.P.'s purported milk allergy. Liacouras Supp. Rep. at 1–2. FPIES "typically occurs in infants less than 9 months of age[,] occurs with the *first ingestion* of the offending antigen" and its symptoms occur "within hours of ingesting the antigen." *Id.* at 1

(emphasis added); M. Michelet et al., *Food Protein-induced Enterocolitis Syndrome-a Review of the Literature with Focus on Clinical Management* 10 J. of Asthma & Allergy 197–207 (2017) filed on Nov. 13, 2017, as Ex. N (ECF No. 77-2); *see also* A. Nowak-Węgrzyn et al., *Non-IgE-mediated Gastrointestinal Food Allergy*, 135 J. Allergy Clinical Immunology 1114–24 (2015) ("Nowak-Węgrzyn") filed on July 7, 2017, as Ex. 35 (ECF No. 70-5).[8] But S.P.'s doctors had noted that she had been consuming significant amounts of milk (and therefore the casein protein contained in milk) for the first 17 months of her life. *See id.* at 1–2 (on July 22, 2011, "[S.P.] was able to consume 4-5 cups/bottles of milk per day" (citing Ex. 2 at 50)). Accordingly, S.P. did not likely suffer from a vaccine-induced casein allergy, given the ample record evidence that S.P could not tolerate milk more than a year after being vaccinated. *See id.*

III. Procedural History

Mrs. Ploughe's initial petition (prepared for her by initial counsel) alleged that S.P. suffered from gastrointestinal problems and papular rash because of the seven vaccines she received on July 22, 2011. Pet. at 1. Within the Petition, however, was an allegation that could be read as also arguing that S.P.'s developmental issues were attributable to these vaccines. *Id.* at 4 ¶ 23. For roughly the next year after the case's initiation, Petitioner filed medical literature and records to support her claim. On October 27, 2015, Petitioner filed an amended petition ((ECF No. 41) ("Amended Petition")), adding the allegations that S.P. suffered a Table injury following her receipt of the varicella vaccine. Amended Petition at 1.

Initial expert reports were filed between December 2015 and the spring of 2016. Thereafter, Special Master Roth (to whom the case was originally assigned) encouraged the parties to informally resolve the dispute. These efforts were unsuccessful; however, a Rule 5 conference was held the following year, on February 7, 2017. (ECF No. 64).

At that time, Special Master Roth noted concerns and issues regarding Petitioner's claim, including (1) "inconsistencies between the medical records and the facts as represented by [Mrs. Ploughe]"; (2) "inconsistencies in [P]etitioner's own facts over the course of these proceedings"; and (3) "prolonged gaps in S.P.'s medical records, during which petitioner claims that S.P. did not receive any treatment [] [which] would be inconsistent with the level of injuries being claimed." Order, dated May 11, 2017 (ECF No. 66), at 1. Special Master Roth also noted a general lack of medical records or testing results that would support Petitioner's contentions, as well as the fact that Dr. Santoro lacked the immunologic credentials to opine on vaccine causation. *Id.* Following the Rule 5 conference, Special Master Roth directed Petitioner to file an expert report that complied

[8] Notably, Nowak-Węgrzyn is also cited by Dr. Obukhanych, and undercuts Petitioner's assertion that S.P. became allergic through a non-IGE-GIFA such as FPIES, FPIAP, or FPE. Nowak-Węgrzyn describes manifestations of FPIES, FPIAP, and FPE. *See* Nowak-Węgrzyn at 2–3. The manifestations are either the same as described by Dr. Liacouras or are more detailed. The descriptions of FPIES, FPIAP, and FPE are not consistent with S.P.'s onset or described symptoms, undermining the contention that S.P. suffered from any of these conditions. *See id.*

with *Althen*, resulting in the filing of Dr. Obukhanych's report. In response, Respondent filed a supplemental report from Dr. Liacouras.

On April 20, 2018 former counsel withdrew from the case, expressly stating her view that "she no longer believes she has a reasonable basis to continue with this claim." *See* March 6, 2018 Motion (ECF No. 85) at 2. Petitioner thus continued as a *pro se* litigant, and filed Dr. Lieberman's report in early 2019. I was assigned to this case in mid-February 2019. (ECF No. 104). Beginning in mid-May 2019, the parties began briefing their positions in anticipation for a ruling on the record. Petitioner's Brief, filed on May 15, 2019 (ECF No. 110); Response, filed on June 7, 2019 (ECF No. 111); Reply, filed on July 1, 2019 (ECF No. 112). Once Petitioner filed her reply, briefing concluded. (ECF No. 112).

IV. Parties' Respective Positions

Petitioner's Brief clarifies her claims that S.P. experienced a milk allergy, rash, and related gastrointestinal issues attributable to the vaccines she received on July 22, 2011. Petitioner's Brief at 1. Petitioner never explicitly lists developmental delay or behavioral issues as an injury, but she does imply that S.P. suffers from some developmental delay or behavioral issues because of her milk allergy and gastrointestinal problems. *Id.* at 1, 10. Regarding her explicit allegations of injury, Petitioner argues that S.P.'s rash was actually varicella, attributable to that vaccine, and that any preexisting rashes were distinguishable. *Id.* at 1–7. Next, Petitioner argues that S.P.'s milk allergy was caused by food proteins contained in vaccines that accidentally immunized S.P. against proteins contained in milk. *Id.* at 10–11. Petitioner primarily relies on the opinion of Dr. Obukhanych to support this allegation. *See id.* Finally, Petitioner argues that S.P.'s gastrointestinal issues are actually part of a non-IgE-GIFA process that is at its root vaccine-caused. *Id.* at 14–15.

Respondent's Brief challenges Petitioner's success in carrying her evidentiary burden. First, Respondent argues Petitioner has not preponderantly demonstrated that the vaccines involved could cause a milk allergy. Response at 11–12 (characterizing Dr. Obukhanych's opinion as conclusory). Next, Respondent contends that Petitioner has not carried her burden of showing that S.P. in fact developed varicella from the varicella vaccine. *Id.* at 12. Finally, Respondent contests Dr. Lieberman's assertion that S.P. suffered from ASD or nervous system injury because of vaccination, noting that vaccine–autism theories have consistently been rejected by courts. *Id.* Respondent also argues that Drs. Lieberman and Obukhanych's theories are generally not credible enough to carry the burden for Petitioner. *Id.* at 13.

Respondent also countered that Petitioner had not satisfied her "did cause" burden, at least with respect to certain of the alleged non-autism injuries. With respect to the allergy injury, he noted that FPIES does not occur when a person has been regularly and continually exposed to an antigen—and yet S.P. had been drinking multiple cups of milk per day up to the time of her second round of vaccinations, and therefore could not be found to suffer from FPIES. Response at 14. There was also no treater or record support for the contention that S.P. had varicella following her

second round of immunizations. *Id.* Finally, Respondent argued that Petitioner had not established onset of S.P.'s injuries in a medically-acceptable timeframe, noting that she relied on temporal association alone. *Id.* at 14–15.

Petitioner's Reply attempts to push back against Respondent's arguments by clarifying her claim and causation theory regarding S.P.'s milk allergy. *See generally* Reply. In this respect, however, the Reply generally focuses on articles and expert reports already submitted, and repeats arguments already made. *Id.* Petitioner also clarifies that her milk-allergy causation theory rests on Dr. Obukhanych's expert report and non-IgE-GIFA mechanism. *Id.* at 2–3. The Reply does not address S.P.'s other alleged injuries.

V. Relevant Law

A. *Petitioner's Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 11(c)(1), 13(a)(1)(A), 14(a); *see also Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[9]

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(a)(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enters. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

[9] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Human Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. App'x 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Human Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Secretary of Health & Human Services*, 418 F.3d 1274, 1278 (Fed. Cir. 2005): "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278.

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Human Servs.*, 121 Fed. Cl. 230, 245 (2015), *vacated on other grounds*, 844 F.3d 1363 (Fed. Cir. 2017).

In discussing the evidentiary standard applicable to the first *Althen* prong, many decisions of the Court of Federal Claims and Federal Circuit have emphasized that petitioners need only establish a causation theory's biological plausibility (and thus need not do so with preponderant proof). *Tarsell v. United States,* 133 Fed. Cl. 782, 792–93 (2017) (special master committed legal error by requiring petitioner to establish first *Althen* prong by preponderance; that standard applied only to second prong and petitioner's overall burden); *Contreras,* 121 Fed. Cl. at 245 ("Plausibility . . . in many cases *may* be enough to satisfy *Althen* prong one." (emphasis in original)); *see also Andreu*, 569 F.3d at 1375. At the same time, there is contrary authority from the Federal Circuit suggesting that the same preponderance standard used overall in evaluating a claimant's success in a Vaccine Act claim is also applied specifically to the first *Althen* prong. *See, e.g.*, *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1350 (Fed. Cir. 2010) (affirming special master's determination that expert "had not provided a 'reliable medical or scientific explanation' *sufficient to prove by a preponderance of the evidence a medical theory* linking the [relevant

vaccine to relevant injury].") (emphasis added). Regardless, one thing remains: petitioners always have the ultimate burden of establishing their Vaccine Act claim *overall* with preponderant evidence. *W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell*, 133 Fed. Cl. at 793 (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *see also Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("[M]edical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" (quoting *Althen*, 418 F.3d at 1280)). Medical records are generally viewed as particularly trustworthy evidence for the "did cause" prong, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Medical records and/or statements of a treating physician's views, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) ("[T]here is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted."). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 742, 749 (2011) (finding that it is not arbitrary or capricious for special masters to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Dept. of Health & Human Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review denied*, 100 Fed. Cl. 344, 356 (2011), *aff'd without op.*, 475 F. App'x 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical

understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.*; *see also Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. denied after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 2013 WL 1896173 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review denied* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Law Governing Analysis of Fact Evidence*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528; *see also Doe/70 v. Sec'y of Health & Human Servs.*, 95 Fed. Cl. 598, 608 (2010) ("Given the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"); *Rickett v. Sec'y of Health & Human Servs.*, 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs.*, No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Human Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[I]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms.").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. denied sub. nom. Murphy v. Sullivan*, 506 U.S. 974 (1992) ("It has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.") (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1948)).

There are, however, situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs.*, 69 Fed. Cl. 775, 779 (2006) ("[L]ike any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking."); *Lowrie*, 2005 WL 6117475, at *19 ("Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent.") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora (such as the district courts). *Daubert* factors are usually employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable and/or could confuse a jury. In Vaccine Program cases, by contrast, these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Human Servs.*, 94 Fed. Cl. 53, 66–67 (2010) ("[U]niquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted."). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of his own in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). But nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Human Servs.*, No. 08-601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review denied*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 Fed. App'x 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters

must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("Assessments as to the reliability of expert testimony often turn on credibility determinations . . . ."); *see also Porter v. Sec'y of Health & Human Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("[T]his court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act.").

D. *Consideration of Medical Literature*

Both parties filed medical and scientific literature in this case, but not every filed item factors into the outcome of this decision. While I have reviewed all of the medical literature submitted in this case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *See Moriarty v. Sec'y of Health & Human Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision.") (citation omitted); *see also Paterek v. Sec'y of Health & Human Servs.*, 527 F. App'x 875, 884 (Fed. Cir. 2013) ("Finding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

E. *Ruling Without Hearing or Argument*

I have opted to decide this case based on written submissions and evidentiary filings, without objection by either party. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions (or components of a claim) on the papers rather than via evidentiary hearing, where (in the exercise of their discretion) they conclude that the former means of adjudication will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The Federal Circuit has recently affirmed this practice. *Kreizenbeck v. Sec'y of Health & Human Servs.*, 945 F.3d 1362, 1365–66 (Fed. Cir. 2020).

ANALYSIS

I. Petitioner Has Not Carried Her Burden of Proof

After careful review of the medical records and Petitioner's filings, I conclude that Petitioner has not established preponderant evidence in favor of her claim.

A. *Alleged Skin Rash Injury*

There are two deficiencies with this aspect of Petitioner's claim. First, it appears more likely than not that S.P.'s rash *preceded* the July 2011 vaccinations. *Compare* Ex. 2 at 50 (noting a rash on S.P.'s back and legs the day of her July 2011 vaccinations), *and* Ex. 2 at 49 (noting "erythematous papules on legs and back" on July 15, 2011, and diagnosing as "viral exanthem"), *with* Ex. 2 at 64–66 (describing S.P.'s rash on August 22, 2011, as a "blanching maculopapular

rash" on the "back, arms, and legs [that] developed two weeks ago" and diagnosing it as viral exanthem). S.P. received a viral exanthem diagnosis both before and after vaccination. It is black-letter law in the Vaccine Program that an injury that precedes vaccination cannot be caused by the later vaccination. *Shalala v. Whitecotton,* 514 U.S. 268, 274–75(1995).[10]

Moreover, even if Petitioner could establish rash onset only after vaccination, she has not offered sufficient reliable and persuasive evidence in support of a Table claim that the varicella vaccine caused varicella in some form. The Vaccine Injury Table includes several possible injuries caused by varicella vaccines. *See* 42 C.F.R. §100.3(a)(x). Two that could possibly describe Petitioner's table allegation are either (a) "[d]issemintated varicella vaccine-strain viral disease," or (b) "[v]aricella vaccine-strain reactivation disease." *Id.* at §100.3(c)(11)–(12) (defining the two injuries). A petitioner must satisfy the relevant Table requirements by a preponderance of the evidence. Section 13(a); *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1572 n.2 (Fed. Cir. 1993).

It is wholly unclear from the pleadings which one Petitioner sought to establish—but the facts of this case support neither. The easiest Table claim to dispose of is the one Petitioner most likely sought to establish, given her focus on rash: a claim regarding "[v]aricella vaccine-strain reactivation disease." To substantiate that injury, "[t]here must be *laboratory confirmation* that the vaccine-strain of the varicella virus is present *in the skin or in any other involved organ.*" 42 C.F.R. §100.3(c)(12) (emphasis added). Here, because no laboratory testing was done to establish the virus's presence, Petitioner cannot succeed on this table claim.

Alternatively, Petitioner might have intended to demonstrate that S.P. suffered from "[d]issemintated varicella vaccine-strain viral disease," in which case "the disease must be demonstrated in the involved organ and not just through mildly abnormal laboratory values." 42 C.F.R. §100.3(c)(11). But Petitioner has not demonstrated that S.P. has suffered from a disease in an involved organ. Rather, Petitioner's Brief, affidavits, and other filings offer nothing more than conclusory allegations that S.P.'s rash was actually varicella. This is underscored by the medical records filed, none of which mention varicella or discuss the possibility that S.P. could have had varicella. In sum, Petitioner has not carried her burden of showing that a Table injury occurred.

Similarly, the argument advanced by Dr. Santoro that S.P.'s rash was GCS that was incorrectly-diagnosed (and hence distinguishable from her preexisting rash) is unpersuasive. Just as the diagnosis of treating physicians is only as good as the logic or bases supporting it, the same is true for experts offering their own counter-diagnosis. *Blackburn v. Sec'y of Health & Human Servs.*, No. 10-410V, 2015 WL 425935, at *19 (Fed. Cl. Spec. Mstr. Jan. 9, 2015) (citing *Snyder*, 88 Fed. Cl. at 743, 745 n.67). Petitioner's expert reports did not provide persuasive bases, whether in the record itself or on other independent and reliable scientific/medical sources, to support an

[10] Petitioner does not allege that any of the vaccines S.P. received in July 2011 significantly aggravated a preexisting rash—and even if she had done so, I could not find on this record that the vaccines made any prior rash worse than it had been or would expected to be.

alternative diagnosis in the face of preponderant record support for the viral exanthem diagnosis. It is also the case that neither Dr. Lieberman—an environmental toxicologist—nor Dr. Santoro—a gastroenterologist—possess the medical expertise to opine on skin conditions or rashes as a general matter.

In sum, S.P. more-likely-than-not had a generic viral exanthem, rather than the proposed alternative diagnoses, that predated the July 2011 vaccinations. Because Petitioner's expert opinions rely on a fact finding supporting such alternative diagnoses, the component of her claim pertaining to the rash cannot succeed. *See Broekelschen*, 618 F.3d at 1350–51. And her experts did not otherwise opine that viral exanthem *could* be vaccine-caused (even if I ignored record evidence establishing the rash actually was present pre-vaccination).

B. *Food Allergy Injury*

Petitioner's claim that S.P.'s purported food allergies are attributable to the July 2011 vaccinations fails on all three *Althen* prongs—but in particular the second and third.

Petitioner maintains that some of the vaccines that S.P. received in July 2011 contained food proteins (casein in particular) to which S.P. is now (purportedly) allergic, and that those components, combined with the adjuvants in the vaccines included to increase immunogenic response, caused S.P. to develop a subsequent reaction to the same proteins in food, perhaps through (as Dr. Obukhanych maintained) FPIES. *See* Petitioner's Brief 11–15; Obukhanych Rep. at 2; Lieberman Rep. at 4. But as Dr. Liacouras established, FPIES cannot reasonably be invoked to explain S.P.'s symptoms, since it "typically occurs in infants less than 9 months of age[,] occurs with the *first ingestion* of the offending antigen," manifests "within hours of ingesting the antigen," and "FPIES to a specific antigen does not occur if that antigen has already been chronically and continually ingested." Liacouras Supp. Rep. at 1–2 (emphasis added) S.P.'s presentation at time of and shortly after her July 2011 vaccination does not support the FPIES theory, as she was then 17 months old (Ex. 2 at 50) and regularly consumed large quantities of milk (*id.* (recording that S.P. was ingesting "4-5 cups/bottles of milk per day" at the time of her vaccinations)), but did not experience anything that could be interpreted as a reaction until at least a day and a half after her July 2011 vaccinations (*id.* at 51 (noting that at her July 22, 2011, well child visit S.P.s vitals were measured at 2:35pm); *id.* at 54 (noting that Petitioner called Sweetgrass at 10:39pm on July 24, 2011, because S.P. began vomiting "that day" and had been vomiting for "8 hours")). As a result, even if it is assumed that a vaccine could provoke an allergic reaction as maintained due to components common to the vaccine and other foods, the facts of this case do not support the conclusion that S.P. did in fact experience such a vaccine-induced allergy.

In addition, S.P. does meet several of the diagnostic criteria for FPIES, such "symptoms occur with the addition of a food antigen that was unknown to the patient and not currently being ingested," nor does she meet the criteria for other non-IgE-GIFA processes. Liacouras Supp. Rep. at 2. The record does not establish *any* food allergy concerns before May 2013, when S.P. was

tested for celiac disease—almost *two years* after the vaccinations at issue. Petitioner has not made a persuasive showing that it would take such a lengthy period of time to manifest an alleged food allergy (especially in light of the fact that the medical history establishes that Petitioner readily sought medical intervention when she had concerns about S.P.'s health).

C. *GI-based Injury*

Petitioner alleges that S.P.'s nonspecific gastrointestinal issues were not only caused by the vaccines received but exacerbated by S.P.'s (also allegedly vaccine-caused) food allergies. But this aspect of her claim fails for the same reasons as stated above. Thus, she has not successfully established, via reliable expert testimony or independent medical/scientific evidence, that vaccines could cause more than transient GI concerns. She also has not demonstrated that she experienced any consistent GI-related problems close in time to vaccination, or over a consistent period (and here, the jump in medical records from late 2011 until 2013 is especially harmful to her claim). At best, she relies on the mere fact that at a time fairly distant from vaccination, S.P. began manifesting some consistent GI-related complaints. But a temporal relationship alone is not enough to satisfy a petitioner's burden of proof. *Veryzer*, 100 Fed. Cl. at 356. This is especially so when the timeframe in question is so attenuated.

II. This Matter was Properly Resolved Without Hearing

In ruling on the record, I am opting against holding a hearing. The choice of how best to resolve this case is a matter that lies generally within my discretion, and neither party objects to my choice in this case, but I shall explain my reasoning nevertheless.

Prior decisions have recognized that a special master's discretion in deciding whether to conduct an evidentiary hearing "is tempered by Vaccine Rule 3(b)," or the duty to afford each party a "full and fair opportunity to present its case." *Hovey v. Sec'y of Health & Human Servs.*, 38 Fed. Cl. 397, 400–01 (citing Rule 3(b)). But that rule also includes the obligation of creation of a record "sufficient to allow review of the special master's decision." *Id.* at 401; *see also Kreizenbeck,* 945 F.3d at 1366. Thus, the fact that a claim is legitimately disputed, such that the special master must exercise his intellectual faculties in order to decide a matter, is not *itself* grounds for a trial (for if it were, trials would be required in every disputed case). Special masters are expressly empowered to resolve fact disputes *without* a hearing—although they should only so act if a party has been given the proper "full and fair" chance to prove their claim.

In this case, no hearing was required to resolve fairly Petitioner's claim. I was able to evaluate the evidentiary strength of her expert's theories and opinions simply based on the written reports, and did not require credibility determinations in weighing the medical/scientific reliability of the theories espoused. The case did not otherwise turn on any fact issues (for example, the ultimate diagnosis or onset) that would have merited allowing live testimony. It was amply

supported by medical records and expert reports as well. Petitioner had a full and fair opportunity to present her claim without a live hearing.

I also take note of the fact that the claim seems originally to have intended, at least in part, to assert a developmental injury caused by vaccination. This kind of claim, in the absence of evidence of encephalopathy (a diagnostic conclusion wholly unsupported by the record), is perilously close to one alleging an autism injury—a category of claim that I have previously noted deserves no further attention from the Vaccine Program (absent some completely new and facially-reliable medical research evidence). *See generally Motuzyuk v. Sec'y of Health & Human Servs.*, No. 18-586V, 2019 WL 1451279, at *5–6 (Fed. Cl. Spec. Mstr. Feb. 14, 2019) (discussing consistent lack of success of autism injury claims). But even with that aspect of the claim shorn from the case, as here, the remaining contentions about allergic response to vaccination are little different from theories that have been routinely rejected when considered in the context of an autism claim. *See, e.g., McKown v. Sec'y of Health & Human Servs.*, No. 15-1451V, 2019 WL 4072113, at *45 (Fed. Cl. Spec. Mstr. July 15, 2019) ("[t]he majority of petitioners have combined an eczema injury claim with the argument that food allergies, or developmental/social delays (and autism), were also vaccine-caused, but none have succeeded"). This case presented theories that have been considered but rejected many times before, and therefore was especially suited for a decision on the record.

CONCLUSION

The Vaccine Act permits me to award compensation only if a Petitioner alleging a "non-Table Injury" can show by medical records or competent medical opinion that the injury was more likely than not vaccine-caused. Here, Petitioner has not established with preponderant evidence that the vaccines S.P. received did cause a rash or food allergies (assuming they *could* do so—something that is also not preponderantly established). I therefore **DENY** entitlement in this case.

In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the Clerk shall enter judgment in accord with this decision.[11]

IT IS SO ORDERED.

Brian H. Corcoran
Chief Special Master

[11] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.